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Atty. Dkt. No. 053466-0325

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Hiroyuki SAITO et al.  
Title: PREVENTION AND TREATMENT OF BLOOD  
COAGULATION-RELATED DISEASES  
Appl. No.: 10/089,501  
371(c) Date: 4/22/2002  
Examiner: Burkhardt, Michael D.  
Art Unit: 1633  
Conf. No.: 9449

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(c), before the mailing date of either a final action under 37 CFR §1.113, a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application.

**RELEVANCE OF EACH DOCUMENT**

All of the documents are in English.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

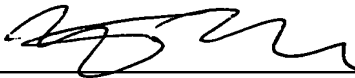
**STATEMENT**

The undersigned hereby states in accordance with 37 CFR §1.97(e)(1) that each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to filing of this Statement.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 19-0741.

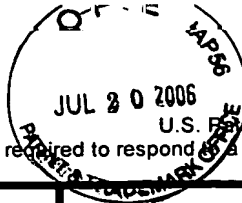
Respectfully submitted,

Date July 20, 2006

By \_\_\_\_\_

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Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

Date Submitted: July 14, 2006

(use as many sheets as necessary)

**Complete if Known**

|                        |                      |
|------------------------|----------------------|
| Application Number     | 10/089,501           |
| Filing Date            | 4/22/2002            |
| First Named Inventor   | Hiroyuki SAITO       |
| Group Art Unit         | 1633                 |
| Examiner Name          | Burkhart, Michael D. |
| Attorney Docket Number | 053466-0325          |

Sheet 1 of 2

**U.S. PATENT DOCUMENTS**

| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | U.S. Patent Document |   | Name of Patentee or Applicant of<br>Cited Document | Date of Publication of<br>Cited Document<br>MM-DD-YYYY | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear |
|-----------------------|--------------------------|----------------------|---|--|--|--|
|                       |                          | Number               | Kind<br>Code <sup>2</sup> (if<br>known) |  |  |  |
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**UNPUBLISHED U.S. PATENT APPLICATION DOCUMENTS**

| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | U.S. Patent Application<br>Document |   | Name of Patentee or Applicant of<br>Cited Document | Filing Date of<br>Cited Document<br>MM-DD-YYYY | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear |
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|                       |                          | Serial Number                       | Kind<br>Code <sup>2</sup> (if<br>known) |  |  |  |
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**FOREIGN PATENT DOCUMENTS**

| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Foreign Patent Document |                     |                                      | Name of Patentee or<br>Applicant of Cited Documents | Date of Publication of<br>Cited Document<br>MM-DD-YYYY | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear | T <sup>6</sup> |
|-----------------------|--------------------------|-------------------------|---------------------|--------------------------------------|---|--|--|----------------|
|                       |                          | Office <sup>3</sup>     | Number <sup>4</sup> | Kind Code <sup>5</sup><br>(if known) |   |  |  |                |
|                       | B1                       | EP                      | 1 069 185           | A                                    | CHUGAI SEIYAKU<br>KABUSHIKI KAISHA                  | 01-17-2001   |  |                |
|                       |                          |                         |                     |                                      |   |  |  |                |
|                       |                          |                         |                     |                                      |   |  |  |                |

**NON PATENT LITERATURE DOCUMENTS**

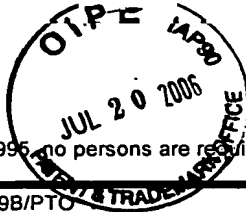
| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the<br>item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s),<br>publisher, city and/or country where published. | T <sup>6</sup> |
|-----------------------|--------------------------|--|----------------|
|                       |                          |  |                |
|                       | B2                       | BROMBERG, M. E., et al., "Role of Tissue Factor in Metastasis: Functions of the Cytoplasmic and<br>Extracellular Domains of the Molecule" TROMBOSIS AND HAEMOSTASIS, STUTTGART, DE, vol. 82, pp.<br>88-92 (July 1999).   |                |
|                       | B3                       | CARMELIET, P., et al., "Molecules in focus. Tissue factor", INTERNATIONAL JOURNAL OF<br>BIOCHEMISTRY AND CELL BIOLOGY, vol. 30, no. 6, pp. 661-667 (June 1998).  |                |
|                       | B4                       | GRAHAM, P. C., et al., "Low levels of tissue factor are compatible with development and hemostasis in<br>mice" JOURNAL OF CLINICAL INVESTIGATION, vol. 101, no. 3, pp. 560-569 (Feb. 1, 1998).   |                |

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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| <b>Substitute for form 1449B/PTO</b><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>Date Submitted: July 20, 2006<br><br>(use as many sheets as necessary) |  | <b>Complete if Known</b>      |                      |
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|  |  | <b>Filing Date</b>            | 4/22/2002            |
|  |  | <b>First Named Inventor</b>   | Hiroyuki SAITO       |
|  |  | <b>Group Art Unit</b>         | 1633                 |
|  |  | <b>Examiner Name</b>          | Burkhart, Michael D. |
| <b>Sheet</b> 2 <b>of</b> 2   |  | <b>Attorney Docket Number</b> | 053466-0325          |

**NON PATENT LITERATURE DOCUMENTS**

| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.                                | T <sup>6</sup> |
|-----------------------|--------------------------|---|----------------|
|                       | B5                       | JANG, I. K., et al., "Antithrombotic effect of a monoclonal antibody against tissue factor in a rabbit model of platelet-mediated arterial thrombosis", ARTERIOSCLEROSIS AND THROMBOSIS: A JOURNAL OF VASCULAR BIOLOGY/AMERICAN HEART ASSOCIATION, vol. 12, no. 8, pp. 948-954 (August 1992). |                |
|                       | B6                       | LEVI, M., et al., "Inhibition of endotoxin-induced activation of coagulation and fibrinolysis by pentoxifylline or by a monoclonal anti-tissue factor antibody in chimpanzees", JOURNAL OF CLINICAL INVESTIGATION, vol. 93, no. 1, pp. 114-120 (1994).  |                |
|                       | B7                       | MASSIMO, R., et al., "Monoclonal antibody against tissue factor shortens tissue plasminogen activator lysis time and prevents reocclusion in a rabbit model of carotid artery thrombosis", CIRCULATION, vol. 93, no. 10, pp. 1913-1918 (1996).  |                |
|                       | B8                       | MELIS, E., et al., "Thrombophilia in mice expressing a tissue factor variant lacking its transmembrane and cytosolic domain" BIOCHEMICAL AND BIOPHYSICAL RESEARCH COMMUNICATIONS, ACADEMIC PRESS INC., Orlando, FL, US, vol. 333, no. 2, pp. 488-495 (July 29, 2005).                         |                |
|                       | B9                       | TAYLOR, F. B, JR., et al., "LETHAL ESCHERICHIA-COLI SEPTIC SHOCK IS PREVENTED BY BLOCKING TISSUE FACTOR WITH MONOCLONAL ANTIBODY", CIRCULATORY SHOCK, vol. 33, no. 3, pp. 127-134 (1991).   |                |

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| <b>Examiner<br/>Signature</b> |  | <b>Date<br/>Considered</b> |  |
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